

# NCI Nanotechnology Grants: Intellectual Property Management

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December 14, 2004

# NIH Sharing Policies and Guidelines

- ❖ Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (1994)  
[http://ott.od.nih.gov/spons\\_research.html](http://ott.od.nih.gov/spons_research.html)
- ❖ Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts (1999)  
<http://ott.od.nih.gov/pdfs/64FR72090.pdf>
- ❖ NIH Data Sharing Policy (2003)  
[http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/)
- ❖ NIH Model Organism Sharing Guidelines (2004)  
[http://grants2.nih.gov/grants/policy/model\\_organism/](http://grants2.nih.gov/grants/policy/model_organism/)

# Intellectual Property Management

- ❖ Intellectual Property (IP) Management Plan
- ❖ Research Resources Sharing Plan
- ❖ Data Sharing Plan
- ❖ Model Organism Sharing Plan

# Intellectual Property Considerations

- ❖ Recognize that inventions may have both commercial **AND** research tool aspects.
- ❖ Assure outside relationships permit the right to distribute research tools, does not hinder academic freedom and assures the right to publish.
- ❖ Strategies for commercial development of inventions.
- ❖ Terms under which research resources will be shared with the research community.

# IP Management Plan

- ❖ Patenting and licensing practices that encourage further commercial development of biomedical inventions.
- ❖ Managing IP to allow access to unique research resources by the research community under reasonable terms.

# IP Management Plan

- ❖ While non exclusive licensing is preferred, exclusive licensing to develop commercial aspects of an invention while allowing for the distribution of research resources may be appropriate.
  - ❖ Rights retained for distributing research resources.
  - ❖ Limited field of exclusive use.
  - ❖ Exclusive licensee will distribute for research use under reasonable terms.

# Research Resources Sharing Plan

- ❖ Include how unique research resources (e.g., biospecimens, biomarkers, cell lines) will be shared with the research community (e.g., supplied by the lab, through a repository, by commercial supplier).
- ❖ Under what terms will the research resources be shared (e.g., UBMTA, SLA, nonexclusive license).

# Data Sharing Plan

- ❖ The expected schedule for sharing data.
- ❖ Format of datasets and availability of analytical tools.
- ❖ Methods of sharing data (e.g., website, personal communication).
- ❖ Criteria and terms of data release (e.g., unrestricted, under an agreement).

# Model Organisms Sharing Plan

- ❖ A Model Organisms Sharing Plan is now an expectation in NIH awards.
- ❖ A plan for sharing model organisms (e.g., mice) should be included if it is anticipated that they will be created under the award.
- ❖ Sharing can be addressed similar to other research resources (e.g., MTA, nonexclusive license).

# Submission of Sharing Plans

- ❖ Data Sharing and Research Resources Sharing plans are expected to be in the application.
- ❖ The Data Sharing Plan will be considered by the review panel.
- ❖ Program staff will consider the adequacy of Data Sharing and Research Resources Sharing plans.
- ❖ The IP Plan is a “just in time” requirement.
- ❖ A Model Organism Sharing Plan is expected in the application if model organism development is anticipated.
- ❖ All final plans must be in place before award.
- ❖ The plans become part of the Terms and Conditions of the award.

# Submission of Sharing Plans

- ❖ Technology Transfer or Sponsored Research offices can provide assistance with the sharing plans
- ❖ Examples of plans can be found at:  
<http://ttb.nci.gov/IPPlans.html>

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